

Amendment under 37 CFR 1.111
USSN 10/521,313

AMENDMENTS TO THE DRAWINGS

Please replace original drawing sheets as follows:

Original drawing sheet 13/18 (Figures 13c and 13d) with attached replacement sheet
13/18 (Figures 13c and 13d); and

Original drawing sheet 14/18 (Figures 14a and 14b), with attached replacement sheet
14/18 (Figures 14a and 14b); and

Original drawing sheet 15/18 (Figures 14c and 15a) with attached replacement sheet
15/18 (Figures 14c and 15a).

Attachment: three (3) Replacement Sheet(s)

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REMARKS

Claims 1-28 are all the claims pending in the application. Claims 4-10 are withdrawn from consideration. Claims 1, 3, 13 and 16 have been amended and claims 19-28 have been newly added. Support for the amendments and new claims may be found at, for example, original claims and the specification. No new matter has been introduced and entry of the amendment is respectfully requested.

English translation of Priority Document

The Office Action has acknowledged all of foreign priority claims and a receipt of a copy of priority document. Applicants submit herewith a sworn English translation of a foreign priority document.

Drawings

Figures 13c, 13d, 14b and 14c have been rejected as they contain typographical errors. In particular, the word "challenge" was pointed out. Applicants submit herewith corrected Figures 13c, 13d, 14b and 14c. Therefore, it is respectfully requested that the rejection of drawings be withdrawn.

Claim rejections under 35 U.S.C. § 112, first and second paragraphs

Claim 16 stands rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to provide an enabling disclosure in commensurate with the scope of claim 16. The Office Action indicates that the specification provides an enabling disclosure to a method applied to rodents.

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Applicants respectfully submit that the disclosure describing experiments carried out in rodents and their results provide an enabling disclosure for currently presented claim 16. It is well known that rodents may be used as an animal model for cancers and produce same or similar immune responses as those of other mammals including human being. The experiments described in the specification of the present application were carried out in a well established animal model for cancers and it is predicted that a mammal would produce same or similar immune responses.

Therefore, the rejection based on lack of enablement is not sustainable and it is respectfully requested that the rejection be withdrawn.

Furthermore, Claims 3 and 16 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to Claim 3, the Office Action asserts that it is unclear whether or not the biological deposit accession numbers recited in the parentheses are actually being claimed or provided only as an example, and suggests amending the claim to read as follows: "The vector of claim 2, wherein the pTV2 vector is pNeuTM deposited at the Korean Culture Center of Microorganisms (KCCM) under the accession number KCCM-10393 and the pCK vector is pCKTM deposited under accession number KCCM-10396."

Claim 3 has been amended as suggested by the Office Action and, thus, the rejection of claim 3 is moot.

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With respect to Claim 16, the Office Action asserts that the claim recites "preventing and/or treating cancer," and it is unclear to the Examiner how the method to treat cancer is to be performed when the cancer has been prevented from arising in the first place. Claim 16 has been amended to recite "preventing or treating cancer." Therefore, the rejection of claim 16 is rendered moot.

Claim rejection under 35 U.S.C. § 102(a)

Claims 1-3, 13 and 16 stand rejected under 35 U.S.C. 102(a) as being anticipated by Lee et al. (Vaccine 21(5-6):521-531, 2003; available online October 9, 2002) ("Lee (2002)").

The Office Action asserts that Lee (2002) teaches a DNA vaccine vector encoding human Her-2/neu (pNeuTM), wherein the vector backbone is a pTV2 vector (pg 522, col. 1, DNA Expression Vectors), as recited in Claims 1 and 13.

It is also asserted that Lee (2002) teaches the use of the human Her-2 gene, wherein the nucleic acid encoding the Her-2/neu polypeptide lacking the intracellular domain is 100% identical to SEQ ID NO:2, as recited in Claim 2.

With respect to Claim 3, the Office Action asserts that Lee (2002) teaches a DNA vaccine vector encoding human Her2/neu (pNeuTM) (pg 521, col. 2, 2).

Lee (2002) also is relied upon to teach a method for preventing tumor growth, wherein laboratory BALB/c mice received three intramuscular injections of DNA vaccine prior to challenge with Her-2+ CT26 colon adenocarcinoma cells (pg 525, col. 2, Section 3.4).

Applicants respectfully submit that the rejection of claims 1-3, 13 and 16 is not sustainable as the present application has an earlier effective filing date than the publication date of Lee (2002).

In response to this, Applicants submit sworn English translations of priority documents KR 10-2002-0041764 and KR 10-20038012. Support for present claims 1-3, 13 and 16 may be found in KR 10-2002-0041764, for example, as follows:

Present Claim 1: page 5, lines 30-33 of KR 10-2002-0041764; Example 1; and Claim 1;

Present Claim 2: page 6, lines 1-5 of KR 10-2002-0041764; Example 1; and Claim 1;

Present Claim 3: page 7, lines 4-7 of KR 10-2002-0041764; and Claim 4;

Present Claim 13: page 5, lines 24-26 of KR 10-2002-0041764; page 7, lines 26-28 of KR 10-2002-0041764; and Claim 7; and

Present Claim 16: page 7, lines 26-30 of KR 10-2002-0041764; page 8, lines 15-19 of KR 10-2002-0041764; Example 4; and Fig. 1b.

Claims 1-3, 13 and 16 rejection under 35 U.S.C. § 103(a)

Claims 1-3, 13, and 16 stand rejected under 35 U.S.C. 103(a) as being obvious over Piechocki et al. (J. Immunol. 167: 3367-3374, 2001) ("Piechocki"), Lee et al. (Biochem. Biophys. Res. Comm. 272(1): 230-235, 2000) ("Lee (2000)"), and Lee (2002).

Piechocki is relied upon to teach the use of a plasmid DNA vaccine encoding a human Her-2/neu polypeptide lacking the intracellular domain. Piechocki is also relied upon to teach a

method of preventing tumor growth, wherein laboratory BALB/c mice received three intramuscular injections of DNA vaccine prior to challenge with Her-2+ D2F2 murine mammary tumor cells (pg 3369, col. 1, Inhibition of Tumor Growth; pg 3371, Figure 3).

The Office Action acknowledged that Piechocki does not teach the use of a pTV2 or pCK vector.

Lee (2000) is relied upon to teach the construction of a pCK expression plasmid that is able to drive high levels of gene expression in vivo for therapeutic use, and Lee (2002) is relied upon to teach a DNA vaccine vector encoding human Her-2/neu (pNeuTM; pg 521, col. 2, 2), wherein the vector backbone is a pTV2 vector.

It is the Office Action's position that it would have been obvious to one of ordinary skill in the art to substitute the expression vector of Piechocki with the pTV2 or pCK expression vectors as taught by Lee (2000, 2002) with a reasonable chance of success because the Lee (2000, 2002) teach the ability of such vectors for use a gene therapy vehicles, in particular considering the fact that Lee (2002) successfully demonstrates the ability to express human Her-2/neu polypeptides lacking the intracellular domain.

With regard to Lee (2002), Applicants respectfully submit that Lee (2002) is not a proper 102(a) reference because Applicant submitted a sworn English translation of KR 2002-0041764, which antedates Lee (2002).

As to Piechocki and Lee (2000), Applicants respectfully submit that these two references do not teach or suggest the elements of the currently presented claims 1, 3, 13s and 16 as well as new claims 19-28, which directly or indirectly depend from claim 1.

That is, none of Piechocki or Lee (2000) teach a pTV2 or pCK vector comprising a nucleotide sequence encoding a truncated human Her-2/neu protein, wherein the truncated human Her-2/neu protein consists of transmembrane and extracellular domains of human Her-2/neu protein, or extracellular domain of the human Her-2/neu protein. Also, Piechocki and Lee (2000) fail to provide one skilled in the art with motivation to employ transmembrane and extracellular domains or extracellular domain of human Her-2/neu protein with reasonable expectation of success.

Applicants note that the Office Action mentions that one of the references has a common inventor with the instant application and constitutes prior art only under 35 U.S.C. 102(e). Applicants do not agree with the Office Action's analysis determining the reference as prior art under 35 U.S.C. § 102(e), as neither of Lee (2000) nor Lee (2002) is a U.S. patent application and the provision of 35 U.S.C. § 102(e) is not applicable.

Claims 1, 11-15 and 17-18 rejection under 35 U.S.C. § 103(a)

Claims 1, 11-15 and 17-18 stand rejected under 35 U.S.C. 103(a) as being obvious over Piechocki, Lee (2000) and Lee (2002), as applied to Claims 1, 13 and 16 above, and in further view of Steinna et al. (U.S. Patent No. 7,005,498 B1) ("Steinna") and Pilon (J. Immunol., 167: 3201-3206, 2001) ("Pilon").

Piechocki, Lee (2000) and Lee (2002) were discussed above.

Steinna is relied upon to teach a DNA vaccine composition comprising a nucleic acid vector encoding a human Her-2/neu polypeptide, wherein the Her-2/neu polypeptide may lack the intracellular domain (col. 24, lines 45-50; col. 31, lines 30-33; cols. 39-40; cols. 65-67,

Example 2). Steinna is also relied upon to teach a DNA vaccine composition including cytokine GM-CSF.

Pilon is relied upon to teach a DNA vaccine composition comprising a nucleic acid encoding a human Her-2/neu polypeptide, wherein the composition further comprised a plasmid expressing the GM-CSF cytokine (pg 3201, col. 2; pg 3202, col. 1, DNA immunization).

The Office Action's position is that it would have been obvious to one of ordinary skill in the art to use a DNA vaccine composition comprising a nucleic acid encoding a cytokine, e.g. GM-CSF, with a reasonable chance of success because the art has long recognized the effectiveness of vaccination to utilize various cytokines, e.g. GM-CSF, and co-stimulatory molecules as molecular adjuvants to evoke a tumor-specific CTL response. (Steinna et al., col. 4, lines 8-10).

Applicants respectfully traverse the rejection for the following reasons. Steinna fails to teach a DNA vaccine containing comprising a nucleotide sequence encoding a truncated human Her-2/neu protein, wherein the truncated human Her-2/neu protein consists of transmembrane and extracellular domains of human Her-2/neu protein, or extracellular domain of the human Her-2/neu protein. Steinna merely describes different domains of the Her-2/neu protein based on primary structure of the protein.

Likewise, Pilon also fails to teach a DNA vaccine containing comprising a nucleotide sequence encoding a truncated human Her-2/neu protein, wherein the truncated human Her-2/neu protein consists of transmembrane and extracellular domains of human Her-2/neu protein,

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or extracellular domain of the human Her-2/neu protein, even though it teaches a plasmid DNA vaccine encoding transmembrane or intracellular domain of human Her-2/neu polypeptide.

The currently presented claim 1 more clearly points out the feature of an embodiment of the present application by reciting "A pTV2 or pCK vector comprising a nucleotide sequence encoding a truncated human Her-2/neu protein, wherein the truncated human Her-2/neu protein consists of transmembrane and extracellular domains of human Her-2/neu protein, or extracellular domain of the human Her-2/neu protein."


Piechocki, Lee (2000), Steinna and Pilon fail to provide one skilled in the art with motivation to employ transmembrane and extracellular domains or extracellular domain of human Her-2/neu protein with reasonable expectation of success.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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